

**510(k) Summary
for the
Range Spinal System: Mesa Modifications**

This 510(k) summary for the Range Spinal System is provided as required per Section 513(i)(3) of the Food, Drug and Cosmetic Act.

1. Submitter :

K2M, Inc.
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Contact Person :

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K2M, Inc.
Telephone: 703-777-3155

Date Prepared: 04/18/12

2. Tradename:

Range Spinal System

Common Name:

Spinal Fixation System

Classification Name:

Pedicle Screw Spinal System (21CFR 888.3070)

Device Product Code:

Spinal Interlaminar Fixation Orthosis (21CFR 888.3050)

Regulatory Class:

MNI, KWP, MNH

Class II

3. Predicate or legally marketed devices which are substantially equivalent :

- K2M Range Spinal System (K042635, K052398, K070229, K072914, K080792, K110991, K112037)
- DePuy Expodium (K090230)
- Medtronic CD Legacy (K020709)
- K2M Mesa Spinal System (K110991)

4. Description of the device:

The Range Spinal System is a top-loading, multiple component, posterior (thoracic-lumbar) spinal fixation system which consists of pedicle screws, rods, locking set screws, hooks, transverse connectors, and rod connectors (axial, parallel and offset lateral). The screws range from 4.5mm to 10.5mm in diameter, 20mm-110mm in length and attach to a 5.5mm rod.

Materials: The devices are manufactured from Titanium Alloy and Cobalt Chrome per ASTM and ISO standards.

Function: The system functions as an adjunct to fusion to provide immobilization and stabilization of the posterior thoracic and lumbar spine.

5. Purpose of Submission:

The modifications to the system include 4.5/5.5mm transition rods as well as additional configurations of hooks, transverse connectors, rod connectors (axial, parallel and offset lateral) and screws that range from 4.0mm-7.5mm in diameter), all of which attach to a 4.5mm rod.

6. Intended Use:

The Range Spinal System is comprised of the DENALI, DENALI DEFORMITY, and MESA Spinal Systems and the ARI Anterior Vertebral Body Staples. The Range 4.5mm Small Stature Rod System is indicated for the following:

Non-cervical, pedicle screw fixation devices for posterior stabilization as an adjunct to fusion for the following indications: trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion. It is also indicated for the treatment of severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 to sacrum) with removal of the implants after the attainment of a solid fusion.

Non-cervical, non-pedicle spinal fixation devices intended for posterior or anterolateral thoracolumbar screw stabilization as an adjunct to fusion for the following indications: degenerative disc disease (DDD) (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e. fracture or dislocation); spinal stenosis; curvatures (i.e. scoliosis, kyphosis; and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion in skeletally mature patients.

7. Comparison of the technological characteristics of the device to predicate and legally marketed devices :

The design features and sizing of the components were compared to predicate devices and the Range Spinal System was found to be substantially the same as these systems.

8. Comparison of the performance data of the device to predicate and legally marketed devices :

The modified implants were tested were tested in static compression, static torsion and dynamic compression in accordance with ASTM F1717 and compared with the original Range Spinal System components. The modified implants were determined to be substantially equivalent to the predicate devices.

9. Conclusion:

There are no significant differences between the Range Spinal System and other systems currently being marketed which would adversely affect the use of the product. It is substantially equivalent to these other devices in design, function, material and intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

K2M, Inc.
% Ms. Nancy Giezen
751 Miller Drive SE, Suite F1
Leesburg, Virginia 20175

MAY 18 2012

Re: K120099

Trade/Device Name: Range Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class II
Product Code: MNI, MNH, KWP
Dated: April 19, 2012
Received: April 20, 2012

Dear Ms. Giezen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120099

Device Name: Range Spinal System

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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Colin O'Neill for RPS
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120079
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